



REMARKS

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Claim 1-2 and 5-8, as amended, and new claims 15-20 appear in the application for the Examiner's reconsideration. Claims 3-4 and 9-14 have been cancelled without prejudice to Applicants' rights to file a divisional or continuation application for the subject matter of these claims. Claim 1 has been amended to correct some minor informalities. Claims 1 and 10 have also been amended to recite that the *ywfL* gene product has been deleted or is essentially non-functional. The amendments are supported by the original claims 3-4 and the specification (page 4, lines 14-16). Claim 1 has been further amended to recite "gene product" rather than "gene." This finds support in the specification (p.4, lines 9-16). New claims 15-20 are directed to the strain where the *ywfL* gene product is deleted, as recited in the original claims. As no new matter has been introduced, the entry of the claim amendments and addition is warranted.

The Examiner states that this application should be a continuation of international application PCT/EP99/06818, rather than a continuation of the U.S. national stage designation of the international application. Applicants respectfully disagree. The U.S. was a designated state during the international application and the present application is a continuation of that designation. Thus, Applicants' statement is accurate as it is referring to the same prior application. For clarity, the term "designation" has been deleted. Applicants have enclosed a certified copy of the priority document in order to perfect the priority claim. In light of this, the Examiner's objection to the specification has also been overcome and should be withdrawn.

The Examiner also objects to the information disclosure statement as improper for the reasons on pp. 3-4 of the Office Action. In response, Applicants are submitting a supplemental information disclosure statement and form PTO-1449 with this amendment. Applicants are also submitting herewith U.S. Patent No. 5,476,773 as an English translation of EPO 0643922. Thus, the objection has been overcome and should be withdrawn.

The Examiner further objects to the drawing for minor informalities. In response, Applicants have corrected the informalities and enclosed the substitute drawings with this amendment.

Claim 1 was objected to because of certain minor informalities. In response, claim 1 has been amended. Thus, the Examiner's objection has been overcome and should be withdrawn.

Claims 1-8 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The Examiner suggests that the recitation of "a bacteria strain of the B. subtilis group..." in claim 1 be changed to "a bacteria strain of B. subtilis ..." to overcome the rejection. In response, Applicants have made the change recommended by the Examiner. Thus, the rejection should be withdrawn.

The Examiner also objects to the recitation "genes involved in the biosynthesis of isovaleric acids..." as being indefinite. In response, Applicants have amended claim 1 as to specifically recite the *ywfl* gene. Thus, the Examiner's rejection has been overcome and should be withdrawn.

The Examiner further objects the recitation in claim 1 of "... substantial amounts of iso-valeric acids ..." as being unclear. Applicants respectfully traverse. The applicants' intent is clear from the present specification, and the present claim language does not cover very small or taste imperceptible amounts of such acids. Furthermore, MPEP section 2173.05 (b) explicitly cites two court decisions which held that the phrases which use the term "substantially" were definite (e.g., "to substantially increase the efficiency of the compound as a copper extractant" and "which produces substantially equal E and H plane illumination patterns"). As is the case in the court decisions cited in the MPEP, one skilled in the art would readily appreciate what is meant by "... substantial amounts of isovaleric acids" in the present application and the claim is definite. Thus, the Examiner's rejection has been overcome and should be withdrawn.

Claim 2 was objected to for the recitation "... taste perceptible amounts of iso-valeric acids." The Examiner states that this limitation is indefinite because "taste is specific to the person that is tasting, and different individuals are able to taste differently." Applicants agree with the Examiner in his statement that taste can vary among individuals, but, the fact that the recitation of "taste perceptible amounts" in claim 2 is subjective does not mean that it is indefinite. It is not necessary to define more accurately the recitation "taste perceptible amount" based on individuals since the present invention is intended for the general public whose taste can be represented by an average person, rather than someone with a peculiar taste. Thus, the Examiner's rejection has been overcome and should be withdrawn.

Lastly, the Examiner objects to the recitation in claim 4 "... wherein the modified gene(s) is derived from the *ywfl* gene" as being unclear. Spherically, the Examiner states that it is not clear what is encompassed by the *ywfl* gene and those modified genes that are derived from the *ywfl* gene. Applicants respectfully traverse. Applicants note that the

sequence of the *ywfL* gene is already known in the state of the art and that a corresponding reference has been indicated in the specification (p.3, lines 28-31; p.4, lines 9-12).

Additionally, Applicants have amended claim 1 to now recite clearly that the *ywfL* gene has been deleted or is essentially non-functional. Thus, the Examiner's objection to the "modified genes" is now moot since that language is no longer included in the claim.

Claim 1-6 and 8 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to convey to one skilled in the art that Applicants had possession of the invention at the time the application was filed. Specifically, the Examiner states that no additional identifying structuring characteristics or properties was described about the bacterial strains of the *B. subtilis* group, other than that the strain cannot produce substantial amounts of iso-valeric acid. Since Applicants have amended claim 1 to now recite implicitly that the bacterial strains contain the *ywfL* gene, there is enough identifying features for the strains and the rejection has been overcome. The Examiner's other rejection that no additional gene or any modifications thereof beyond the *ywfL* gene and its deletion was described has been rendered moot. This is so because Applicants have amended to claim 1 to explicitly recite the *ywfL* gene and its deletion. Thus, the Examiner's rejections have been overcome and should be withdrawn.

Claims 1-6 and 8 were rejected under 35 U.S.C. 112, first paragraph. Specifically, the Examiner states that the specification, while enabling for a *B. subtilis* strain, wherein the *ywfL* gene has been deleted, such that the strain cannot produce substantial amounts of iso-valeric acid, does not enable for any bacterial strain of the *B. subtilis* group, wherein one or more genes involved in the biosynthesis of isovaleric acids have been modified such that the strain cannot produce substantial amount of isovaleric acid.

Applicants submit that the modification of a *ywfL* gene product to render it essentially non-functional is also enabled since the modification would have the same effect as deleting the *ywfL* gene product. As explained in the present specification, the gene products, preferably a *ywfL* gene product, may comprise polypeptides acting as enzymes within the synthesis pathway or acting as regulatory agents for the production of iso-valeric acids. The specification further teaches that in a preferred embodiment the *ywfL* gene may be deleted from the genome or is modified such that the gene is not transcribed into a functional protein (p.4, lines 9-16). When a *ywfL* gene product is modified to become essentially non-functional, i.e., a functional protein is not produced, it prevents the iso-valeric acid from being formed. Thus, the specification enables a *B. subtilis* strain, wherein the *ywfL* gene has been modified as to render it essentially non-functional.



Applicants appreciate the Examiner's conceding that the specification is enabling regarding a *B. subtilis* strain, wherein the *ywfL* gene has been deleted, such that the strain cannot produce substantial amounts of iso-valeric acid. This feature of the invention is specifically covered by new claims 15-20. Thus, the rejection is not applicable to those claims and they are in condition for allowance.

Claims 1-3, 5, 6 and 8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese patent No. 55004382 to Sekiguchi et al. (hereafter "Sekiguchi"). Applicants respectfully traverse.

Sekiguchi teaches a method of fermenting soybeans with *Bacillus natto* in the presence of gluconic acid and gluconolactone to produce natto. The gluconate improves natto flavor and aroma by inhibiting formation of iso-valeric acid (abstract).

In contrast, the present invention relates to novel strains of *B. subtilis* such as *Bacillus natto*, in which the *ywfL* gene has been deleted or is essentially non-functional, such that the strain cannot produce substantial amount of iso-valeric acid (see amended claim 1).

Sekiguchi made no mention of neither the *ywfL* gene, or its being deleted or rendered non-functional to inhibit the production of iso-valeric acid. One skilled in the art, guided by the teaching of the reference, would not have achieved the present invention. In fact, Sekiguchi teaches away from the present invention since it uses an entirely different approach, i.e., by inclusion of a chemical, than that of the present invention which modifies the genes, to solve the problem of iso-valeric acid impacting on the taste of food material. Thus, Sekiguchi does not render the present invention obvious and the Examiner's rejection should be withdrawn.

It is believed that the application is now in condition for allowance, early notification of such would be appreciated. Should the Examiner not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the claims.

Respectfully submitted,

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